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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,643	10/20/2000	Pramod K. Srivastava	8449-073-999	8419
20583	7590	07/28/2004	EXAMINER	
JONES DAY			YAEN, CHRISTOPHER H	
222 EAST 41ST ST			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	

1642

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/693,643

**Applicant(s)**

SRIVASTAVA, PRAMOD K.

**Examiner**

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,9,13,17,21,25-42,44,46,47,82-91 and 93-111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,9,13,17,21,25-42,44,46,47,82-91 and 93-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

**Re: Srivastava P**

**Priority Date: 20 October 2000**

1. The amendment filed 5/3/2004 is acknowledged and entered into the record. Accordingly, claims 1-3,5-8,10-12,14-16,18-20,22-24,43, 45,48-81, and 92 are canceled without prejudice or disclaimer, and claims 107-111 are newly added.
2. Claims 4,9,13,17,21,25-42,44,46-47,82-91, and 93-111 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***New Argument***

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

4. Claims 4,9,13,17,21,25-42,44, 47,82-91,93-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. Applicant amends the claims to recite a method of "inhibiting" cancer (particularly in claims 4 and 47). However, this recited limitation is not supported in the specification as filed. The specification teaches methods of treating or preventing, but makes not mention of "inhibiting" as claimed. The term "inhibiting" and "preventing" encompass different scopes. For example, according

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to Merriam-Webster Online (see attached print outs from [www.M-W.com](http://www.M-W.com)), *inhibit* means to restrain or to hold in check, while the term *prevent* means to hold or keep back, hinder or stop. In essence, to inhibit carries a lesser degree of impedance. Although the difference is subtle, the distinction between the two terms has not been conveyed in the specification to support the interchanging of preventing with inhibiting.

***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

5. The rejection of claims 4,9,13,17,21,25-42,44,47,82-91, 93-106 and now newly added claims 107-111 under 35 USC 112, 1<sup>st</sup> paragraph is maintained for the reasons of record. The rejection of claim 46 was in error and is duly noted, thus the rejection is withdrawn for claim 46. Applicant states that the removal of the term “preventing” obviates the rejection. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The claims to some extent still read on prevention because of the administration of a “vaccine”. The specification alludes to vaccine compositions as those that are useful for the prevention of a malignant disease (see for example page 8, lines 15-24). Since the specification has not clearly delineated a difference between a vaccine and a composition, the “vaccine” administered is assumed to be for a preventative therapies. Thus the rejection under 35 USC 112, 1<sup>st</sup> paragraph as lacking enablement is maintained for the reasons of record.

It is noted that this rejection may be overcome if applicant amends the claims to recite a method of administering a “composition”.

***Claim Rejections Maintained - 35 USC § 102***

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6. The rejection of claims 4,9,13,27,30,33,42,44,46,82,86,90,93,94,95,97, 100,101 and now newly added claims 107 and 111 under 35 USC 102(b) as being anticipated by Chen *et al* is maintained for the reasons of record. Applicant's amendment to the claims to include the limitation of unbound heat shock protein, or heat shock protein bound to a molecule that does not display the immunogenicity of the component does not overcome the prior art, because Chen *et al* still teaches an "unbound heat shock protein" as currently claimed. Newly added claims 107 and 111 are anticipated because the limitation of inducing or increasing an immune response in a subject against the "component" is also taught by Chen *et al* (see page 1038, in particular, where it is taught that the administration of the E7-HSP70 enhanced the anti-tumor immunity). Thus the rejection under 35 USC 102(b) as being anticipated by Chen *et al* is maintained.

***Claim Rejections Maintained - 35 USC § 103***

7. The rejection of claims 4,9,33,42,44,46,82,86,90,94,95, 97 and now newly added claims 107 and 111 under 35 USC 103(a) as being obvious over Chen *et al* is maintained for the reasons of record. Applicant's arguments are identical to those argued for the 102(b) rejection, *supra*. Applicant's amendment to the claims to include the limitation of unbound heat shock protein, or heat shock protein bound to a molecule that does not display the immunogenicity of the component does not overcome the prior art, because Chen *et al* still teaches an "unbound heat shock protein" as currently

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claimed. Newly added claims 107 and 111 are anticipated because the limitation of inducing or increasing an immune response in a subject against the "component" is also taught by Chen *et al* (see page 1038, in particular, where it is taught that the administration of the E7-HSP70 enhanced the anti-tumor immunity). Thus the rejection under 35 USC 103(a) as being obvious over Chen *et al* is maintained.

### ***Conclusion***

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
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July 14, 2004

  
**GARY NICKOL**  
**PRIMARY EXAMINER**